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October 11, 1999

Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fisher's Lane, Room 1061
Rockville, MD 20852

Re: Proposed Regulations pertaining to Surgeon's and Patients Examination Gloves

Dear Sir:

On behalf of our client, Magla Products, Inc., we set forth below our comments regarding the proposed rules pertaining to the above captioned merchandise, published in the Federal Register on July 30, 1999 (64 Fed. Reg. 41709 *et seq.*) Magla Products is an importer of large volumes of patients examination gloves, which it distributes to national retail chains that sell the product to the general public.

Mandatory Limits to and Proposed Labeling of Amount of Powder: The proposal is to limit to 120 mg. the amount of particulate weight on each glove and to require the maximum actual particulate weight to be set forth on the principal display panel of the packaging. We do not for the purpose of this submission address the amount of the proposed limit. However, the requirement to state actuals is as a practical matter impossible to satisfy; even if it were, the cost of accurately stating actuals would be prohibitive. Should the proposed labeling be adopted, prudent distributors would state in essence merely that the actual maximum does not exceed the FDA maximum.

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There is a great demand in this country for patient examination gloves. They are produced in lots ranging from several hundred thousand to over one million, but are often packaged for retail in quantities of 100 per package. No manufacturer can produce gloves with a homogeneous distribution of powder and there will be substantial variation as to powder in a production run. In addition, while gloves are often imported prepackaged, they are also imported in bulk. It will be economically prohibitive, if not impossible, to require distributors to monitor actual powder content down to groupings of 100 in retail packaging. Further, there will be variances within each package, as powder will be lost or redistributed during transit and while in storage; for example, the powder will migrate towards the lower portion of the retail package over time. We therefore suggest that the FDA's prime objective in this area, of limiting total particulate content, will be satisfied with the requirement for a statement that they not exceed a given maximum, as with a phrase such as, "Meets FDA Limits of no more than 120 mg. Powder per Glove.".

Under the current proposal, a prudent distributor, mindful of the variations which will occur, will be forced to state on the proposed labeling simply that the actual powder on the gloves does not exceed 120 mg. per glove. It is nothing more than conjecture that there will be a marked consumer preference for gloves with a lesser powder content than recommended as a maximum by the FDA, (for otherwise consumers would expect that the FDA would have recommended a lower maximum). By the same token, there is a need to make packaging uniform for very large quantities of gloves produced. There is a desire to comport to the FDA regulations and a need to insure that statements made as to powder content will not be subject to challenge as a result of expected variations in powder content. This will force the use of a statement that means nothing more than the powder content of the gloves is within the FDA maximum. We therefor suggest that if a maximum powder content be imposed, there is nonetheless no need for additional labeling. IF the FDA deems some labeling to be necessary, it be limited to a statement that the gloves meet FDA maximum of 120 mg. Powder content per glove. We note that the inclusion of such a statement will enhance FDA's jurisdiction to enforce the maximum to the same extent as would exist with the proposed labeling.

Mandatory Limits to and Proposed Labeling of Amount of Extractable Protein: The comments as to variability of powder apply to this area as well. Latex is a natural product and as such, there is are natural variations in content, in this case, in amount of extractable protein. Compounding the natural variation is the fact that virtually all manufacturers use production methods which differ to some degree and affect the amount of water extractable protein. Aside from being able to take reasonable steps to insure that the maximum proposed by the FDA are not exceeded, the distributors have no way to control or state on a package by package basis the amount of extractable protein. We suggest that the maximum be a requirement that, if imposed, need not be accompanied

by any required labeling, or that such labeling be limited to a statement that the gloves meet FDA maximums of 1,200 mcg per glove. Again, the inclusion of such a statement will enhance FDA's jurisdiction to enforce the maximum to the same extent as would exist with regard to the proposed labeling.

Expiration Dating: We find that the proposal is unclear in a number of respects. Each style is to be tested to determine its expiry date but what is a "style"? Is each production run of a style to be tested? What defines "failure" and hence expiry date? For example, it could be a rate of tear or leakage. It could be a failure to meet as yet undefined criteria for a given percentage of the gloves which are tested, but if so, what will the percentage be?

Aside from this, it will be impossible to perform adequate testing when the testing is to be based on a combination of accelerated and "real time" testing. There is an insufficient period within which to test in real time: the FDA's stated it expects that it in the usual case the expiration date will extend on the average to three years from the date of production but contemplates a two years before implementation of the new regulations. Moreover, the FDA acknowledges there to be no accepted protocol for accelerated ageing. Further, as to gloves imported in bulk from different manufacturers (which will have different production dates), it will be impossible to uniformly state expiration date, and uniformity in packaging is essential for the maintenance of the product as a low-cost consumer item.

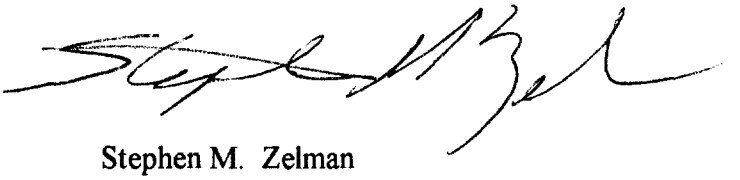
In addition, expiration date defined by whatever standard is adopted will vary after distribution for sale to the ultimate consumers by a number of factors beyond the control of the manufacturer or distributor. For example, storage in sunlight of gloves which are packed in clear plastic bags, or where temperature conditions vary significantly, will contribute substantially to the degradation of the gloves. An expiry date determined by whatever acceptable testing is adopted might well be in excess of the date an unacceptably high failure rate will actually occur, leading to a false sense of security on the part of the consumers.

In short, the determination of an expiration date based on testing is certainly premature at this time given the absence of accepted standards and test procedures. We believe that labeling for expiration date could well be misleading and will impose a high cost with no real benefit. However, there is every incentive on the part of all parties concerned to shorten the time between production and distribution. Indication of a stated date of latest production can be expected to steer the consumers towards the gloves which were produced most recently, and those gloves will naturally experience the least amount of degradation due to the passage of time. We reiterate our position that

at this point that time dating is neither warranted, necessary nor beneficial. However, if the FDA feels that the consumers should have some indication of the age of the gloves, the labels can include a phrase such as, "Produced no later than_____." If such labeling is adopted, it must be understood that the date of production must be allowed to run beyond the date of actual distribution to permit the purchase of sufficient quantities of packaging in advance and also to avoid wastage of packaging due to unexpected temporary decreases in demand.

Other Concerns: It is at best premature at this time to consider the eventual prohibition of the sale of powdered gloves, at least as present technology allows the powder free gloves to be produced. There is a clear desire of the consumers for powdered gloves, as expressed in their choice of the product over the powder free alternatives.

Respectfully submitted,



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on behalf of Magla Products, Inc.

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